

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BIOGEN INTERNATIONAL GMBH)	
and BIOGEN MA INC.,)	
)	
Plaintiffs,)	Civil Action No. 17-823-MN (Cons.)
)	
v.)	
)	
AMNEAL PHARMACEUTICALS LLC,)	
et al.)	
)	
Defendants.)	
)	

**DEFENDANTS' REPLY TO BIOGEN'S RESPONSIVE POST-TRIAL BRIEF ON
VALIDITY OF THE '514 PATENT**

I. INTRODUCTION

For the first time, in its responsive post-trial brief, Biogen argues that claim 11 of the '514 patent and its dependent claims do not require the administration of DMF to be therapeutically effective. Biogen Resp. Br., D.I. 359 at 18. Perhaps because it strains credulity to argue that a “method of treating a subject in need of treatment for multiple sclerosis” need not be effective, Biogen has never made the argument before. This argument is both waived and judicially estopped. Until now, Biogen consistently took precisely the opposite position—that claim 11 requires therapeutic effectiveness.

II. ARGUMENT

Biogen’s responsive brief takes a new position that claim 11 and its dependent claims do not require the claimed method to be “therapeutically effective” and “simply requires a method of treating one in need of MS treatment by ‘orally administering to the subject about 480 mg/day’ of DMF.” Biogen Resp. Br., D.I. 359 at 18. Not only does Biogen’s new argument contravene the fundamental nature of treatment, i.e., which is necessarily effective, it is the opposite of the position Biogen has always maintained throughout this litigation.

Previously, Biogen consistently argued that all the asserted claims of the '514 patent require a “therapeutically effective” dose of 480 mg/day. In its response to Defendants’ contention interrogatory requesting Biogen’s invalidity positions “on a claim-by-claim basis,” Biogen did not differentiate claim 11 and responded that “the '514 patent claims include three elements: (i) treating MS; (ii) by administering a *therapeutically effective* amount of DMF..., and (3) wherein the *therapeutically effective amount* is about 480 mg/day. Ex. B, Supp. Resp. ROG #9 at 9, 15 (emphasis added). In its pre-trial briefing, Biogen took the same position. D.I. 335, Ex. 2 at ¶ 79; *see also* ¶ 5. Biogen did so to support its argument that the asserted claims would have been nonobvious to a POSA. *Id.* ¶ 79. Indeed, in its obviousness analysis, Biogen listed claim 11

among the claims that require the elements of “a therapeutically effective amount of dimethyl fumarate” and “the therapeutically effective amount of dimethyl fumarate is about 480 mg/day.” *Id.* headings at pgs. 80, 96. Even in the same post-trial brief, Biogen collapsed the non-obviousness analysis for all asserted claims into a single inquiry that analyzed which “effective doses” were taught by the prior art. Biogen Resp. Br., D.I. 359 at 27-28.

Both parties litigated written description with the mutual understanding that all asserted claims required the claimed method of treating MS to be therapeutically effective. At trial, Biogen never treated claim 11 differently from the others. When the Court understood that the claims require that the 480 mg/day dose “has to be therapeutically effective,” Biogen did not argue otherwise. Tr. 926:24-927:11. In fact, Biogen responded to the Court’s inquiry, conceding that on the issue of written description, the claims “would rise and fall together because of the elements.” Tr. 910:11-21. Biogen responded to the Court as follows:

THE COURT: So if one, if claim 1, for example, doesn't meet the written description, you would agree that this others don't, and if claim 1 does, you would agree that the others do as well.

MR. MONROE: Yes, Your Honor...

Tr. 910:22-911:1.

Biogen has waved this new argument. *Inline Connection Corp. v. EarthLink, Inc.*, 684 F. Supp. 2d 496, 511 (D. Del. 2010). “[A] litigant cannot strategically lie behind the log until after the trial and receipt of evidence, argument ... before raising an issue not found in the pleadings nor included in the pre-trial order and then raise it when it is too late for his opponent to do anything about it. The manifest prejudice of such tactics would make a shambles of the efficacy of pre-trial orders and a fair trial.” *Id.* at n.46 (quoting *Bettes v. Stonewall Ins. Co.*, 480 F.2d 92, 94 (5th Cir. 1973)). This case is similar to *Inline*, which involved “a theory not appropriately presented at trial” that “the court decline[d] to consider.” *Id.* at 511.

Biogen is also judicially estopped from taking its new position that claim 11 does not require therapeutic efficacy. “[A]bsent any good explanation, a party should not be allowed to gain an advantage by litigation on one theory, and then seek an inconsistent advantage by pursuing an incompatible theory.” *Krystal Cadillac-Oldsmobile GMC Truck, Inc. v. General Motors Corp.*, 337 F.3d 314, 319 (3d Cir. 2003) (internal quotations omitted). “Though there is no rigid test for judicial estoppel, three factors inform a federal court’s decision whether to apply it: there must be (1) irreconcilably inconsistent positions; (2) adopted . . . in bad faith; and (3) a showing that . . . estoppel . . . address[es] the harm and . . . no lesser sanction [is] sufficient.” *Endo Pharms. Inc. v. Mylan Pharms. Inc.*, No. 11-CV-00717 (RMB/KW), 2014 WL 334178, at *9 (D. Del. Jan. 28, 2014), *vacated on other grounds*, 2014 WL 2532179 (D. Del. Apr. 8, 2014). Biogen’s new position is irreconcilably inconsistent with what it represented to the Court. There can be no good-faith explanation for Biogen’s contradictory position. Biogen cannot now change course post-trial to try to save the ’514 patent from inadequate written description.

Defendants will be prejudiced if Biogen is permitted to change its position on claim 11. The parties tried the case under the mutual understanding that all asserted claims required the method to be therapeutically effective, and the parties never litigated a claim that did not require the method to actually be effective. Defendants relied upon Biogen’s undisputed position, were deprived of the opportunity to present evidence relating to this new theory, and a record was never created to refute Biogen’s new erroneous position. Just as in the *Inline* case, “had [Defendants’] been aware of [Biogen’s] current argument, [Defendants] would have analyzed it and might have modified [their] trial strategy.” *Inline*, 684 F. Supp. 2d at 510. Litigating the issue now post-trial would only delay the Court’s resolution of the invalidity of the ’514 patent, which after June 20, 2020, is the only impediment to the launch of Defendants’ generic products.

III. CONCLUSION

The Court should reject Biogen's new argument based on waiver and judicial estoppel.

Respectfully,

/s/ Stephen B. Brauerman

Stephen B. Brauerman (#4952)
BAYARD, P.A.
600 N. King Street, Suite 400
Wilmington, DE 19801
(302) 655-5000
sbrauerman@bayardlaw.com
*Attorney for Defendants Hetero USA Inc.,
Hetero Labs Limited Unit-III, and Hetero
Labs Limited, and Shilpa Medicare Limited*

Respectfully,

/s/ John C. Phillips, Jr.

John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
PHILLIPS, GOLDMAN, MCLAUGHLIN
& HALL, P.A.
1200 North Broom Street
Wilmington, DE 19806-4204
(302) 655-4200
jcp@pgmhlaw.com
dab@pgmhlaw.com
*Attorneys for Defendants MSN
Laboratories Private Ltd. and MSN
Pharmaceuticals Inc., Sandoz Inc. and
Prinston Pharmaceutical Inc., and Zydus
Pharmaceuticals (USA) Inc.*

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